Docket No.: 1422-0625P
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Makoto OZEKI et al.

Application No.: 10/790,730 | Confirmation No.: 2621

Filed: March 3, 2004 | Art Unit: 1617

For: PHARMACEUTICAL COMPOSITION FOR TREATING MOOD DISORDERS | Examiner: D. R. Claytor

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Makoto Ozeki, Tsutomu Okubo and Lekh Raj Juneja, hereby declare and say as follows:

1. We are familiar with the subject matter of the above-identified application (United States Serial Number 10/790,730). We are the inventors of the subject matter claimed in the present application.

2. The Examiner has cited JP Application No. 2001-253740 (JP '740) as prior art against the present claims. JP '740 lists four inventors as Makoto Koseki, Tsutomu Okubo, Lekh Raj Juneja and Nagahiro Yamazaki. However, two errors in this listing of inventors hide the fact that JP

'740 represents our own work. First, the last name of Makoto "Ozeki" is misspelled as "Koseki." Second, Nagahiro Yamazaki is not an inventor of the subject matter disclosed in JP '740. Nagahiro Yamazaki was erroneously listed as an inventor at the time of filing the Japanese application and is thus erroneously listed as an inventor of JP '740. Nagahiro Yamazaki did not have an inventive role in the research which led to JP '740 or the present application. Thus, Nagahiro Yamazaki is not an inventor of the presently claimed subject matter regardless of the erroneous listing as an inventor in the JP '740 publication.

3. The undersigned declare further that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S. Code 1001 and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

21/2/2007
Date

Makoto Ozeki
Makoto Ozeki

21/2/2007
Date

Tsutomu Okubo
Tsutomu Okubo

21/2/2007
Date

Lekh Raj Juneja
Lekh Raj Juneja

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Sir:

1. We, Makoto Ozeki, Tsutomu Okubo and Lekh Raj Juneja, hereby declare and say as follows:

2. We are the listed Inventors of the subject matter disclosed and claimed in the above-identified U.S. Patent application and we are familiar with the prosecution history of the application.

3. We understand that the Examiner has made a rejection of the claims over Blum et al. (U.S. Patent 6,132,724) in view of Kent et al. (J. Affect Dis. 73 (2003); 211-221). It is our understanding that the Kent reference has an effective prior art publication date of 2003.

4. We conceived and reduced to practice the invention claimed in the above-referenced application prior to the 2003 publication date of the Kent reference. As evidence of prior invention, the following items are attached:

5. Exhibit 1.1 is a copy of JP 2001-253740 (JP '740), filed in Japan on August 24, 2001. Exhibit 1.2 is an English translation of JP '740.

6. JP '740 represents work which we had actually reduced to practice prior to the filing date of JP '740 on August 24, 2001 in Japan. For instance, we reference Test Example 1 as an accurate description of actual tests performed to examine the therapeutic effects of a composition containing theanine on mood disorders. This Test Example 1 represents the actual work carried out on a group of 24 normofolatemic patients. Other work was actually reduced to practice, and is represented by additional Test Examples in JP '740, however, we will only concentrate on the work conducted and subsequently set forth in Test Example 1 at this time.

7. As seen in Test Example 1 of JP '740, in diagnosis, the patients were assessed to be mild to severe according to the diagnostic criteria of DMS III R (Diagnostic and Statistical Manual of Mental Disorders, 3rd Ed. Rev American Psychiatric Association, Washington D.C., pp. 235-253, 1987). The test was conducted in double blind, and the test period was 3 weeks. The 24 patients (average body weight: 61 kg) were divided into two even groups according to the above diagnostic results. One group was administered with a theanine-formulated tablet (group administered with the theanine-formulated tablet). This theanine-formulated tablet (see Example 1 of JP '740) was prepared by mixing the raw materials given below, and granulating to provide a tablet: frosted sugar: 71.67% by weight (0.5375 g), trehalose: 10% by weight (0.075 g), L-theanine: 13.33% by weight (0.1 g), sucrose fatty acid ester: 1% by weight (0.0075 g), and lemon flavor: 4% by weight (0.03 g), for a total of 100% by weight (0.75 g). The other group was administered with a control

tablet (group administered with the control tablet). The control tablets were prepared as outlined in Comparative Example 1 of JP '740.

8. As conducted and shown in Test Example 1 of JP '740, each patient was administered with one tablet twice a day, at 10 am and 4 pm (amount of theanine intake: 200 mg). The therapeutic effects were assessed according to the Hamilton scale consisting of 21 items regarding the assessment for depression. The assessment was made before the intake of each tablet (i.e. before the beginning of the test) and on Day 7, Day 14 and Day 21 from the intake, during each of the days, respectively.

9. A progressive change in the average score of the Hamilton scale for each of the group of the patients administered with the theanine-formulated tablet and the group administered with the control tablet resulted. These results were actually obtained and were subsequently illustrated in FIG. 1 of JP '740. The average score of the Hamilton scale was significantly decreased from "24" before the intake to "15" after 3 weeks of the intake in the group administered with the theanine-formulated tablet ($p<0.01$), while a reduction in the score in the group administered with the control tablet was hardly recognized. By the intake of the theanine-formulated tablet, the therapeutic effects were observed as early as after 1 week from the intake.

10. As illustrated in Table 1 of JP '740, significant amelioration in the symptoms "1. depressed mood," "2. feelings of guilt," "3. suicide," "8. retardation: psychomotor," and "16. diminished insight" were recognized on Day 7, Day 14 and Day 21 in the group administered with the theanine-formulated tablet. These symptoms are characteristics of the patients with depression

or in a depressed mood. On the other hand, no amelioration in every symptom was observed in the group administered with the control tablet.

11. Accordingly, JP '740 is evidence that we actually reduced to practice the present invention prior to the 2003 publication of Kent.

12. The undersigned declare further that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S. Code 1001 and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

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